DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
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VIA FEDERAL EXPRESS

February 17, 2005

Mr. Cory Berg, President
Quality Liquid Feeds
3586 State Road 23N
P.O. Box 240
Dodgeville, WI 53533

WARNING LETTER CIN-05-23745

Dear Mr. Berg:

FDA conducted an inspection of your medicated feed mill in Wellsville, OH between the dates of September 21 through September 28, 2004. The inspection revealed significant deviations from Title 21 Code of Federal Regulations, Part 225, Current Good Manufacturing Practice for Medicated Feeds (CGMPs), 21 CFR 225 and 21 CFR 558.311, approval for lasalocid.

The inspection of your facility was conducted as a pre-license inspection. As such, the investigator inspected your facility using the regulations appropriate for a licensed feed mill as well as those for an un-licensed feed mill.

Section 501(a)(2)(B) of the Act, states that a drug shall be deemed adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with CGMP, to assure that such feed meets the requirements of the Act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess. The investigator documented the following deviation from the CGMPs:

- Results of laboratory assays of drug components indicated that medicated feed was not in accord with the permissible limits, and no investigation and corrective action was implemented immediately. [21 CFR 225.158]

Specifically, testing (April 2004) of two feeds containing lasalocid were found to be out of limits. The test results were obtained in September 2004, but an investigation was not conducted immediately, as required by 21 CFR 225.158. This deviation causes the medicated feed you manufactured to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

In addition, further review of the documents collected during the inspection revealed the following:

You are currently manufacturing a Type B liquid feed from Type A medicated article with the following specifications for your feeds:

Type B Feed	Type A Article	21 CFR [pH range]	Your SOP Range	Your Range in Practice
Arba-vue hfr24-12B160	Lasalocid	558.311 [4.0-8.0]	[redacted]	[redacted]

Our investigation documented that the pH of your product falls outside the limits designated in the respective section of 21 CFR 558.311.

Under 21 CFR 558.311, the manufacture of this feed at a pH other than that listed in the regulation requires that you: 1) either file a New Animal Drug Application (NADA) for the product or establish a master file containing data to support the stability of the product, 2) authorize the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish physical stability, and 3) request the sponsor of an approved NADA to file a supplement to provide for the use of its lasalocid Type A article in the manufacture of the liquid Type B feed specified in the appropriate master file. You currently do not have an approved NADA on file for this product. You have not established a master file and the sponsor has not filed a supplement to its NADA to provide for the use of its Type A medicated article in your Type B liquid feed.

For this reason, the medicated feeds you manufactured are unsafe under Section 512(a)(2) of the Act because they bear or contain an unapproved new animal drug. The feed is thus adulterated under 501(a)(6) of the Act.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of animal drugs, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. Approval of medicated feed mill licenses will be refused until the CGMP deviations noted above are corrected.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. You may address your reply to Stephen J. Rabe, Compliance Officer, at the above address or at 513-679-2700 ext 163.

Sincerely,

Carol A. Heppe
District Director

Cc: Darin W. Porter